K132278

510(k) Summary

In accordance with the Safe Medical Devices Act (SMDA) of 1990 and Title of the Code of Federal Regulations Part 807 (21 CFR §807), and in particular §807.92, the following summary of safety and effectiveness information is provided.

Submitted by:

Cochlear Americas
13059 East Peakview Ave.
Centennial, CO 80111

SEP 2 6 2013

On behalf of:

Cochlear Bone Anchored Solutions AB
Konstruktionsvägen 14
SE-435 33 Mölnlycke
Sweden

Contact Persons:

Sean Bundy
Sr. Manager, Regulatory Affairs and Compliance
Phone: 303-524-7139
Facsimile: 303-524-6825
Email: SBundy@cochlear.com

Date Submission Prepared:

July 2013

Device Name:

Trade or Proprietary Name:	Cochlear Baha® 4 Sound Processor
Common or Usual Name:	Bone Anchored Sound Processor
Classification Status:	Class II, 21 CFR §874.3300
Product Codes:	LXB
Panel:	Ear Nose and Throat Devices Panel

Device Description:

The subject of this **Special 510(k): Device Modification** is a modification to the Cochlear BP100 sound processor, which was cleared under 510(k) K090720 for unilateral or bilateral use with conductive and mixed hearing losses (as a result of congenital malformations such as atresia, or certain medical conditions such as chronic suppurative otitis media), and for cases of single-sided sensorineural deafness (SSD, caused by a congenital condition, surgery, trauma or disease). The Baha system has been marketed for more than 30 years throughout the world, and there are now more than 100,000 users of a Baha system globally.

Baha sound processors can be used with either the external Baha headband or Softband in persons of any age, or for children aged 5 or older with the Baha auditory osseointegrated implants. The external Baha headband or Softband system works via conventional transcutaneous bone conduction amplification. The Baha implant system works by combining the external sound processor with an abutment and a small titanium implant placed in the skull behind the ear in a simple surgical procedure. The system is based on the process of "osseointegration" through which living tissue integrates with titanium in the implant. Thus, the titanium implant becomes one with the surrounding bone, allowing high-quality amplified and processed sound from the Baha sound processor to be conducted via the skull bone directly to a cochlea with residual functionality. For either form of transmission, the processed sound either bypasses a conductive block in those patients with conductive or mixed hearing loss, or transfers sound through the skull to the opposite-ear normal cochlea for patients with SSD.

The modified sound processor, the Baha 4 is an upgrade to the currently marketed Baha BP100 sound processor, which it will replace on the U.S. market. The Baha 4 sound processor is mechanically identical to the BP100, but replaces the ASIC inside the processor with an off-the-shelf electronic assembly used in currently marketed air conduction devices. The modified device utilizes the same fundamental scientific principles, and has the same intended use and indications for use as the current legally marketed device it will replace. In addition, the Baha 4 is compatible with certain 2.4GHz devices currently marketed for use with air conduction hearing aids.

Intended Use:

The new Baha 4 will be used as an external sound processor option (in the Cochlear Baha family of sound processors) to conduct sound energy directly to the cochlea via a Baha auditory osseointegrated implant, or via transcutaneous transmission with a Baha headband or Softband. This is the same intended use, and for the same patient population, as the current legally marketed, unmodified Baha BP100 device (the predicate device that it will replace).

Technological Characteristics:

The modified sound processor will still be compatible with the currently marketed Softband/headband (cleared under K002913 and letters to file under this clearance), and the currently marketed auditory osseointegrated implant (BIA300 system, cleared under K100360 and BA400 cleared under K121317), and will also be backward compatible with the original auditory osseointegrated implant (cleared under K955713).

The primary modifications proposed are technological improvements so that the Baha 4 can take advantage of several features that are inherent to the new electronic assembly. These include:

- 2.4GHz wireless audio and data connection capability
- One additional program slot (for a total of 4)
- Wind noise detection and reduction
- 17-channel sound analysis
- Automatic scene analysis

The Baha Fitting Software (also cleared under K090720) has been updated to incorporate support for communication with the new electronic assembly, as well as allowing the fitting audiologist to enable or disable features of the new electronic assembly.

Conclusions:

Despite technological improvements and the upgrade to new sound processing features, the Baha 4 sound processor still has substantially equivalent function and technology, and the same intended use as the predicate Baha BP100 sound processor cleared for marketing under K090720. The indication for use statement is also the same as that for the current legally marketed Baha BP100 sound processor that it will replace.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 26,2013

Cochlear Americas
% Mr. Sean Bundy
Director, Regulatory Strategy, Cochlear Americas
13059 E Peakview Ave
Centennial, CO 80111

Re: K132278
Trade/Device Name: Baha 4 Sound Processor
Regulation Number: 21 CFR 874.3300
Regulation Name: Hearing Aid
Regulatory Class: Class II
Product Code: LXB
Dated: August 27, 2013
Received: August 27, 2013

Dear Mr. Bundy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K 132278

Device Name: Cochlear Baha® 4 Sound Processor

Indications for Use Statement:

The Cochlear Baha® 4 sound processor has the following indications for use:

- Patients of any age for use with the Baha Softband or headband. Patients aged 5 and older for use with the Baha auditory osseointegrated implant system.
- Patients who have a conductive or mixed hearing loss and can still benefit from sound amplification. The pure tone average bone-conduction hearing threshold (measured at 0.5, 1, 2, and 3 kHz) should be better than or equal to 45 dB HL.
- Bilateral fitting is intended for patients who meet the criterion in both ears, with bilaterally symmetric moderate to severe conductive or mixed hearing loss. Symmetrical bone-conduction thresholds are defined as less than a 10 dB average difference between ears (measured at 0.5, 1, 2, and 3 kHz), or less than a 15 dB difference at individual frequencies.
- Patients who suffer from unilateral sensorineural deafness in one ear with normal hearing in the other ear (i.e. Single-Sided Deafness; SSD). Normal hearing is defined as a pure tone average air-conduction hearing threshold (measured at 0.5, 1, 2, and 3 kHz) of better than or equal to 20 dB HL.
- Baha for SSD is also indicated for any patient who is indicated for an air-conduction contralateral routing of signals (AC CROS) hearing aid, but who for some reason cannot or will not use an AC CROS.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____

(21 CFR 801 Subpart C) (Part 21 CFR 801 Subpart D)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sageev George -S
2013.09.26 11:53:19
-04'00'